

MAERTENS et al.
Appl. No. 09/973,025
March 1, 2005
Rule 312 Amendment
VIA FACSIMILE to 7038729306
Examiner's Tel. No.: 571-2720904

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amendment.
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5/23/2005

AMENDMENTS TO THE CLAIMS:

The following claim amendments are proposed to place the application in condition for allowance.

Claims 1-99. (Canceled)

100. (Previously Presented) An isolated E2 specific monoclonal antibody, said antibody specifically binding to at least one region within a domain spanning amino acids 416-650 or 655-809 of the hepatitis C virus polypotein

101. (Previously Presented) The monoclonal antibody according to claim 100 or 113 which has been produced from a mammal immunized with a composition comprising purified recombinant HCV single or specific oligomeric recombinant E2 envelope proteins.

102. (Previously Presented) The monoclonal antibody according to claim 101 wherein said recombinant HCV E2 envelope proteins are produced by a recombinant mammalian cell.

103. (Previously Presented) The monoclonal antibody of claim 102 wherein said mammalian cell is infected with recombinant vaccinia virus carrying DNA for expressing said HCV E2 envelope proteins.

104. (Previously Presented) The monoclonal antibody according to claim 101 wherein said recombinant HCV E2 envelope proteins are produced by a recombinant yeast cell.

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105. (Previously Presented) The monoclonal antibody according to claim 101 wherein said recombinant HCV E2 envelope proteins are the expression product of at least one of the following recombinant vectors:

a) a recombinant vector comprising a vector sequence, a prokaryotic, eukaryotic or viral promoter sequence followed by a nucleotide sequence encoding said single or specific oligomeric E2 protein;

b) a recombinant vector according to (a), with said nucleotide sequence being characterized further in that it encodes a single HCV E2 protein starting in the region between amino acid positions 290 and 406 and ending in the region between amino acid positions 600 and 820;

c) a recombinant vector according to (b), with said nucleotide sequence being characterized further in that it ends at any of amino acid positions 623, 650, 661, 673, 710, 715, 720, 746 or 809;

d) a recombinant vector according to any one of (b)-(c), said nucleotide sequence further comprising a 5'-terminal ATG codon and a 3'-terminal stop codon; and

e) a recombinant vector according to any one of (b)-(d) further comprising a factor Xa cleavage site and/or 3 to 10 histidine codons positioned 3'-terminally to said nucleotide sequence.

106. (Previously Presented) Kit for determining the presence of HCV antigens present in a biological sample, comprising:

at least one E2 specific monoclonal antibody according to claim 100 or 113,

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a buffer or components necessary for producing the buffer enabling binding reaction between these antibodies and the HCV antigens present in said biological sample,

a means for detecting the immune complexes formed in the preceding binding reaction.

107. (Previously Presented) An isolated antibody of claim 101 which is an E2 specific monoclonal antibody.

108. (Previously Presented) The isolated protein of claim 101 wherein said E2 protein is at least 90% pure.

109. (Previously Presented) The isolated protein of claim 101 wherein said E2 protein is at least 95% pure.

110. (Previously Presented) The isolated protein of claim 101 wherein said E2 protein is at least 97% pure.

111. (Previously Presented) The isolated antibody of claim 101 wherein said E2 protein is at least 97% pure.

112. (Previously Presented) The isolated antibody of claim 101 wherein said E2 protein is at least 99% pure.

113. (Previously Presented) An isolated monoclonal antibody binds to the same epitope as the E2 specific monoclonal antibody according to claim 100.

114. (Previously Presented) The isolated E2 specific monoclonal antibody secreted by the hybridoma cell line deposited December 3, 1998 with the European Collection of Cell Cultures and assigned the accession number 98031215 or a

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hybridoma cell line selected from deposit accession numbers DSM ACC 2616 or DSM ACC 2615, each of which were deposited September 10, 2003 with DSMZ.

115. (Currently Amended) ~~An isolated A-isolated~~ E2 specific monoclonal antibody ~~which of claim 100, wherein said antibody~~ specifically binds to a region in the E2 domain spanning an amino acid segment selected from the group consisting of 409-428 (SEQ ID NO:73), 427-446 (SEQ ID NO: 74), 439-458 (SEQ ID NO:75), 451-470 (SEQ ID NO:76), 463-482 (SEQ ID NO:77), 475-494 (SEQ ID NO:78), 487-508 (SEQ ID NO:79), 499-518 (SEQ ID NO:80), 511-530 (SEQ ID NO:81), 523-542 (SEQ ID NO:82), 547-566 (SEQ ID NO:83), 559-578 (SEQ ID NO: 84), 571-590 (SEQ ID NO:85), 583-602 (SEQ ID NO:86), 595-614 (SEQ ID NO:87), 607-626 (SEQ ID NO:88), 619-638 (SEQ ID NO:89), 631-650 (SEQ ID NO:90) and 655-674 (SEQ ID NO:92).

116. (Currently Amended) An isolated monoclonal antibody which binds to the same epitope as the E2 specific monoclonal antibody of claim 114.

117. (Previously Presented) The monoclonal antibody according to claim 100 or 113 which has been produced from a mammal immunized with a composition comprising at least one purified recombinant HCV single or specific oligomeric recombinant E2 envelope protein.